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IN THE
Supreme Court of the United States

LITTLE SISTERS OF THE POOR HOME FOR THE AGED, DENVER, COLORADO, *et al.*,
Petitioners,

v.

SYLVIA BURWELL, *et al.*,
Respondents.

On Writs of Certiorari to the United States Courts of Appeals for the Third, Fifth, Tenth and District of Columbia Circuits

BRIEF OF *AMICUS CURIAE* WOMEN SPEAK FOR THEMSELVES IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Women Speak for Themselves is a project of the Chiaroscuro Institute and a membership organization of more than 43,000 American women who have signed an open letter opposing the contraception and emergency contraception mandate ("the Mandate")[2] issued by the Department of Health and Human Services ("HHS"), because the Mandate threatens religious freedom and proposes a reductionist and harmful understanding of women's freedom. Members of Women Speak for Themselves bring fact-based and nonpartisan arguments about women's freedom and about religious freedom to their local communities, and to the federal government.

SUMMARY OF THE ARGUMENT

I. The government has not demonstrated a "compelling state interest" sufficient under this Court's opinions to permit it to burden the free exercise rights of individuals or institutions under the Religious Freedom Restoration Act ("RFRA"),[3] by forcing them to obtain insurance coverage of

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[1] No counsel for a party authored this brief in whole or in part. Printing costs for this brief were provided by the members of Women Speak for Themselves. A blanket consent from all parties, consenting to the filing of this brief, has been submitted to the Clerk.

[2] 45 C.F.R. 147.130(a)(1)(iv) (2013) (HHS); 29 C.F.R. 2590.715-2713(a)(1)(iv) (2013) (Labor); 26 C.F.R. 54.9815-2713(a)(1)(iv) (2013).

[3] Religious Freedom Restoration Act, Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified in scattered sections of 5 and 42 U.S.C.).

contraception, as well as emergency contraception ("ECs"). The government has not met its burden of demonstrating that it is seeking to accomplish an interest it regards as of the highest order, particularly in light of the tens of millions of Americans already exempted from the Mandate. Nor has it met its burden to demonstrate specifically that the Mandate will improve women's health or equal access to health services. The government further cannot show a compelling interest in administering a comprehensive regulatory scheme, nor that female employees affected by the requested exemption are impermissibly burdened.

II. The government is asking this Court to accept its intuition that free contraception and ECs will lower rates of unintended pregnancy and abortion and thereby improve women's health. On its face, this seems plausible, even likely, but relevant data and the history of contraception's dynamic effects in the United States do not bear it out. To the contrary, the evidence shows that the government wrongly presumes that what contraception and ECs are designed to do on an individual scale – prevent the conception or birth of a child – they will do on a social scale. The sources upon which the government relies do not support any link in the chain of causation required to make the government's case. Other sources confirm this failure. To wit, the government does not and cannot show that: the Mandate will cause an increase in the usage of contraceptives and ECs; that increased usage will bring about lower rates of unintended pregnancy, abortion or contraindicated pregnancies; or that unintended pregnancy causes particular health problems for women. Nor does the government

demonstrate that any incidental health benefits contraception might offer outweigh acknowledged health risks contraceptives can pose to women individually and socially.

III. The government claims that the Mandate promotes gender equality respecting health expenses, but its sources do not show that contraceptives account for differential health costs between men and women. Reliable governmental sources point to factors other than contraception.

ARGUMENT

I. THE GOVERNMENT HAS FAILED TO DEMONSTRATE THAT THE MANDATE SERVES A "COMPELLING INTEREST" ACCORDING TO THIS COURT'S DECISIONS.

The Religious Freedom Restoration Act ("RFRA") forbids the federal government from substantially burdening the exercise of religion unless the burden furthers a compelling governmental interest.[4] This requirement obtains even if the "burden results from a rule of general applicability."[5] This brief does not take up the matter of the Mandate's substantial burden on the exercise of religion. It rather shows that the government cannot demonstrate that the Mandate serves a "compelling interest" Neither the government's regulations, nor its briefs, nor the Institute of Medicine Report (commissioned by HHS to provide substantive recommendations for its regulations concerning preventive health care for women) on which the government so regularly relies – *Clinical Preventive Services for Women: Closing the Gap* ("IOM Report")[6] – demonstrate such an interest.

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[4] 42 U.S.C. § 2000bb-1(b) (2012).

[5] 42 U.S.C. § 2000bb-1(a) (2012).

[6] Inst. of Med., (2011).

In each of the instant cases, the government bears the burden of "going forward with the evidence and of persuasion"[7] about the existence of a "paramount interest"[8] of the state. It cannot – as it has attempted in the course of litigation over the Mandate – continually alter its alleged objectives, but must show that an alleged objective was the lawmaker's "'actual purpose'" at the time of passage.[9] It has to show that this interest is satisfied by applying the challenged law to "the particular claimant whose sincere exercise of religion is being substantially burdened."[10] It must do more than express "broadly formulated interests."[11] If the challenged law contains exemptions for others, this is evidence that it does not "protect[] an interest 'of the highest order'...when it leaves appreciable damage to that supposedly vital interest unprohibited."[12]

The Mandate fails this test for four reasons. First, the government's exempting tens of millions of persons from the Mandate reveals its own conviction that the Mandate is not highly important to the government, let alone "compelling" These exemptions and their legal consequences under RFRA are addressed fully in the Briefs for

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[7] *Gonzales v. O Centro Esprita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428 (2006) (citation omitted).

[8] *Sherbert v. Verner*, 374 U.S. 398, 406 (1963) (quotation omitted).

[9] *Shaw v. Hunt*, 517 U.S. 899, 908, n.4 (1996) (citation omitted).

[10] *Gonzales*, 546 U.S. at 430-31.

[11] *Id.* at 431.

[12] *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 547 (1993) (quoting *Florida Star v. B. J. F.*, 491 U.S. 524, 541-42 (1989) (Scalia, J., concurring in part and concurring in judgment)).

Petitioners before this Court.[13] Furthermore, it is highly significant that the U.S. Preventive Services Task Force – the body to whom the Institute of Medicine made its recommendations, and the highest governmental medical expertise in the United States respecting necessary "preventive care" – has, even to this moment, *not* recommended contraception as preventive medical care for women.[14]

Second, the government has not demonstrated that the Mandate forwards its declared interests in the manner required by *Wisconsin v. Yoder*,[15] *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*,[16] and *Brown v. Entertainment Merchants Association*.[17] The government cannot demonstrate a substantial or causal connection between the Mandate and its claimed health outcomes. (Section II.) *Yoder* – which applied the weaker pre-RFRA strict scrutiny standard – requires the state to show evidence which is "specific," not "speculative" or based upon "assumptions," and not contradicted by

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[13] *See* Br. for Pet. in *East Texas Baptist University v. Sylvia Burwell*, No. 15-35; *Little Sisters of the Poor Home for the Aged v. Sylvia Burwell*, No. 15-105, *Southern Nazarene Univ. v. Sylvia Burwell*, No. 15-119, and *Geneva College v. Sylvia Burwell*, No. 15-191 (U.S. Sup. Ct., Jan. 4, 2016), 59-68; and Br. for Pet. in *David A. Zubik v. Sylvia Burwell*, No 14-1418, *Priests for Life v. Department of Health & Human Services*, No. 14-1453, *Roman Catholic Archbishop of Washington v. Sylvia Burwell*, No. 14-1505 (U.S. Sup. Ct., Jan. 4, 2016), 56-63.

[14] U.S. Preventive Services Task Force, *Published Recommendations (current as of January 2016).*

[15] 406 U.S. 205, 222 (1971).

[16] 546 U.S. 418 (2006).

[17] 131 S. Ct. 2729 (2011).

the historical record.[18] *Gonzales* requires the state to show "with more particularity," how even an "admittedly strong interest," would be adversely affected by granting an exemption to the particular plaintiffs.[19] *Brown* requires that the state "specifically identify an 'actual problem' in need of solving," and show that the burden on the constitutional right is "actually necessary" to the solution.[20] It may not make a merely "predictive judgment" about a causal link based upon competing and contradictory studies.[21] It may not rely upon "ambiguous proof,"[22] but must "prove" that the matter it regulates is the "cause" of the harm it seeks to prevent. Evidence of mere "correlation" is insufficient, as are studies with "significant, admitted flaws in methodology."[23] Even if the state proves causation, evidence that the claimed effects are "small" and "indistinguishable" from effects produced by things *not* regulated, renders the legislation "underinclusive."[24] The state must finally show more than a "modest gap" (20% in *Brown*) between the government's goal and the current situation; "the government does not have a compelling interest in each marginal percentage point by which its goals are advanced."[25] Though *Brown* considered protected speech, not religious exercise, its standards apply in this case because the government here stakes its "compelling interest"

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[18] *Yoder*, 406 U.S. at 226-27.
[19] *Gonzales*, 546 U.S. at 431.
[20] *Brown*, 131 S. Ct. at 2738.
[21] *Id.*
[22] *Id.* at 2739.
[23] *Id.*
[24] *Id.* at 2740.
[25] *Id.* at 2741, n.9.

argument upon empirical claims, and *Brown* is this Court's most complete guide for assessing such arguments. In short, the government has opened the door to scrutiny of its empirical claims by grounding its compelling interest argument so firmly upon them in its regulations, [26] in its briefs since the beginning of Mandate litigation, and in the IOM Report upon which both so heavily rely.

Under Yoder, Gonzales and *Brown*, the government has failed to demonstrate a compelling state interest in applying the Mandate to the religiously objecting parties. The government uses an uncertain measure of "unintended pregnancy," and offers a merely "predictive" and "speculative" proposal of causation between free contraception and women's health. (Section II.) The government rests its findings about women's health on a very few studies which do not support its causal claims; it ignores competing sources – including federal governmental sources – which link contraception with health risks to women. Furthermore, although contraceptive use is already very high among the women the Mandate targets, the government proposes to close a relatively small (11%) gap in usage with regulations which would not only fail to affect the women experiencing the highest rates of unintended pregnancy (the poor), but also several other groups of women who eschew or distrust contraceptives: those for whom contraceptives are medically contraindicated; those who object on religious or moral grounds; and those who fear or have experienced adverse health or other side

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[26] 77 Fed. Reg. 8725, 8727-28 (Feb. 12, 2012), and 78 Fed. Reg. 39870, 39872-73 (July 2, 2013).

effects. Regarding these women, the Mandate not only fails to sufficiently acknowledge contraception's negative effects, but also the many reasons *other* than cost why various women avoid contraception. In an environment where the vast majority of sexually active women use contraception already, the government has demonstrated nothing more than the theoretical possibility that the Mandate might increase contraceptive usage by some tiny amount. This is legally insufficient. (Section II. A.)

Even if the Mandate could increase usage among any group of women, there is no evidence that this would lower rates of unintended pregnancy or abortion. Unintended pregnancy rates in the U.S. have risen over the past decades *alongside* increased usage and availability of contraception. They are in fact *highest* among women receiving free or low-cost contraception via government programs.[27] There is evidence that state level contraception mandates enacted over the last 20 years have not lowered unintended pregnancy and abortion rates in the relevant jurisdictions.[28] Further, rates of unintended pregnancy and abortion respond to a wide variety of variables. Credible analyses, including a study co-authored by Federal Reserve Chair Janet Yellen,[29] show that "risk compensation" effects, among other reasons, have produced and may continue to produce

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[27] Guttmacher Institute, *Fact Sheet: Unintended Pregnancy in the United States* (July, 2015).

[28] Michael J. New, *Analyzing the Impact of State Level Contraceptive Mandates on Public Health Outcomes*, 13 Ave Maria L. Rev. 345, 368 (2015).

[29] George A. Akerlof, Janet L. Yellen & Michael L. Katz, *An Analysis of Out-of-Wedlock Childbearing in the United States*, 111 Q.J. Econ. 277 (1996).

higher, not lower rates of unintended pregnancies and abortions in response to changes in the "marketplaces" for relationships and marriage facilitated by the separation of sex from procreation. Also, contraceptive failure rates are significant. (Section II.B.)

Finally, even if the government could show that the Mandate could increase contraceptive usage *and* reduce rates of unintended pregnancies, they have not demonstrated a causal relationship between unintended pregnancies and women's health. The government's cited sources and others strongly suggest mere correlation, or reverse causation, or even the presence of a third factor which could drive both unintended pregnancies and particular health outcomes. (Section II.C.)

In sum, the government's argument is exactly the kind of "ambiguous" and "speculative" proof that *Brown* and *Yoder* reject. It lacks the "particularity" demanded by *Gonzales* and the empirical strength required by *Brown*. The government also fails the *Brown* test of "underinclusivity" given that laws addressing matters the government leaves *unregulated* might better ameliorate women's health and health care costs. The government could devote more resources, for example, to addressing the leading causes of women's premature death, none of which are related to contraceptives' availability.[30] It

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[30] Committee on Population: Division of Behavioral and Social Sciences and Education: Board on Health Care Services (National Research Council: Institute of Medicine), *Measuring the Risks and Causes of Premature Death: Summary of Workshops* (Feb. 2015), http://www.ncbi.nlm.nih.gov/books/NBK279981/.

could promote better coverage of maternity costs – a leading driver of differential health costs between males and females of childbearing ages[31] – or even of children's health care costs, given women's vastly higher rates of single parenting.[32]

To the extent that the government intends the Mandate to further its interest in reducing unintended pregnancy by moving more women to more effective long-acting reversible contraceptives ("LARCs"), [33] its plan is based upon the false assumptions that LARCs are far more expensive, and that women targeted by the Mandate will more often adopt them. HHS' agency, the National Institutes of Health, explicitly and significantly doubts the efficacy of this strategy, on the basis of hormonal contraception's adverse health and other side effects, and on the basis of women's lengthy historical resistance to LARCs.[34] (Section II.A.)

Third, although this Court in *United States v. Lee*[35] refused to create exemptions from participation in the federal tax system – in light of its actuarial

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[31] Ctrs. for Medicare & Medicaid Servs., National Health Care Spending by Gender and Age, 2004 Highlights (2004), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/2004GenderandAgeHighlights.pdf.

[32] Jonathan Vespa et al., (U.S. Census Bureau), *America's Families and Living Arrangements: 2012*, 12, Table 4 (2013).

[33] 78 Fed. Reg. 39870, 39873, n. 23 (July 2, 2013).

[34] Dep't of Health and Human Servs.,The National Institutes of Health, *Female Contraceptive Development Program (U01)*, at http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html.

[35] 455 U.S. 252 (1982).

complexity, the necessity of its maintaining fiscal vitality, and the likelihood of inviting myriad claims from a wide variety of religious traditions – the government cannot here claim a compelling governmental interest in administrative efficiency of the kind at issue in *Lee*. Though the Internal Revenue Service ("IRS") will administer penalties for noncompliance with the Mandate, the social security and national taxation systems at issue in *Lee* are not at all analogous to the private business-to-business insurance transactions the Mandate compels. The government's granting an exemption from the Mandate is nothing like Congress or the IRS compromising the "fiscal vitality" of the nation's tax system. [36] In fact, the government has already conceded this by granting exemptions affecting tens of millions of Americans. Furthermore, unlike the tax system at issue in *Lee*, the Mandate was not legislated by Congress, but is rather a discretionary HHS initiative (relying upon the recommendations of a conspicuously ideological IOM committee[37]). There is also no likelihood of a "slippery slope," as in *Lee*. An exemption from insuring contraception is not at all analogous to absolving employers from tax liability which funds employees' retirements. The government concedes that the vast majority of employers voluntarily cover contraception, [38] and

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[36] *Id.* at 258-59.

[37] Letter from Anna Franzonello, Ams. United for Life, to Ctrs. for Medicare and Medicaid Servs. (Sept. 29, 2011), http://www.freedom2care.org/docLib/20110929_AmericansUnitedforLifepreventiveservicescomment.pdf.

[38] Press Release, Dep't of Health & Human Servs., *A Statement by U.S. Dept. of Health and Human Services Kathleen Sebelius*

holds that contraception coverage is cheaper than the insurance costs relative to born children.[39] Finally, as with the Amish in *Yoder*, only a "readily identifiable"[40] and discrete group of religious citizens and institutions opposes contraceptive coverage.

Fourth, the requested accommodation is not subject to *Lee's dicta* that employers risk "imposing religion" on their employees by depriving them of certain legislatively mandated "benefits" [41] *Lee* concerned employees' social security taxes and benefits. As this Court recognized in *Hobby Lobby*, if *Lee*'s *dicta* were extended to every single item the government denominated a "benefit", the government could require religious employers to insure for third trimester abortions and every other procedure legal in the relevant state.[42] RFRA would be nullified. Rather, the Court should consider the compelling need – or not – of each *particular* mandated benefit for *particular* employees. Here, the government has already conceded that an exemption from providing this benefit does not significantly burden nonbeneficiaries, by means of the volume of exemptions it has allowed. Finally, contraception is ubiquitous, widely used and relatively inexpensive.[43]

(Jan. 20, 2012), http://www.hhs.gov/news/press/2012pres/01/20120120a.html.

[39] 78 Fed. Reg. at 39872, and 77 Fed. Reg. at 8727.

[40] *Lee*, 455 U.S. at 261.

[41] *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005).

[42] *Hobby Lobby*, 134 S. Ct. at 2783.

[43] *See generally* Kimberly Palmer, *The Real Cost of Birth Control*, U.S. News & World Rep. (Mar. 5, 2012), http://money.usnews.com/money/blogs/alpha-consumer/2012/03/05/the-real-cost-of-birth-control. *See e.g.* http://www.walmart.com/ip/Plan-B-One-Step-Emergency-Contraceptive-Levonorgestrel-Tablet-1.5-mg/29131740

It is not analogous to a stream of social security benefits over the course of an employee's entire retirement.

II. THE GOVERNMENT HAS FAILED TO DEMONSTRATE A CAUSAL RELATIONSHIP BETWEEN THE MANDATE AND IMPROVED HEALTH FOR WOMEN.

The government's Brief in Opposition asserts very generally – by way of references to, *inter alia,* the IOM Report, Justice Ginsburg's dissent in *Hobby Lobby*, and opinions from the courts below – that contraception avoids unintended pregnancies and associated health risks, assists the health of women with conditions contraindicating for pregnancy, and reduces abortions. [44] Its published regulations specified these claims further, and also regularly rely upon similar assertions in the IOM Report.[45]

It is striking, however, how few sources the government relies upon for its sweeping claims across all of these documents. And the sources it does employ are either irrelevant or insufficient. The government also avoids mentioning even *governmentally produced findings* which contradict its claims, and instead asks this Court simply to agree with its seemingly logical prediction that widespread free contraception and ECs *must* accomplish on a national level what they are

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(Walmart Corporation's online birth-control sales reveal prices ranging from nine dollars for one month of birth control pills, to forty-nine dollars for emergency contraception).

[44] Br. in Opp. 20.

[45] *See* 78 Fed. Reg. 39870, 39872-73.

designed to do for each individual. The material below establishes that the government has not and cannot demonstrate this. Thus it has failed to meet its burden to demonstrate a "compelling interest"

A. The government does not show that the Mandate will cause increased usage of contraceptives or ECs, especially among women at risk for unintended pregnancy and abortion.

The government claims that cost is a significant barrier to use of contraceptives and ECs such that insurance coverage without cost-sharing will increase usage.[46] There are myriad problems with this contention. First, the IOM Report and its sources acknowledge that contraceptive usage is already extremely high, having been used by 99% of women who have "ever" had sex, and 89% of currently sexually-active women.[47]

Second, because the Mandate is directed to employed women and daughters of the employed, it will largely affect women who already have relatively easy access to contraception and use it. Women above 150% of the poverty line and more-educated women are more likely to use contraception

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[46] 78 Fed. Reg. at 39,873.

[47] IOM Report at103; and William D. Mosher & Jo Jones, U.S. Dep't of Health and Human Servs., *Use of Contraception in the U.S.: 1982-2008*, 5, 9 (2010). *See also* Kimberly Daniels, William D. Mosher & Jo Jones, *Contraceptive Methods Women Have Ever Used: United States 1982-2010*, Nat'l Health Stat. Rep. (Feb. 2013).

than are less-advantaged women.[48] On these facts, it is difficult to imagine how the Mandate could increase the usage rates of its target audience much if at all.

Furthermore, evidence indicates that "cost" plays a small role in women's decisions about contraception. In Centers for Disease Control ("CDC") data cited in the IOM Report, cost does not even make the list of "frequently cited reasons for nonuse" among the 11% of sexually-active women not using contraception.[49] In a Guttmacher source the IOM Report overlooked,[50] only 3.7% of the total sample of women seeking abortions listed cost as a barrier to contraceptive usage; and this study did not investigate whether the women citing cost were eligible for the many extant programs offering free or low-cost contraception.

It appears that women currently eschewing contraception base their rejection upon contraception's side-effects, health risks, and failure rates. HHS has bluntly conceded this point in a 2014 request for proposals to develop new, nonhormonal forms of contraception.[51] There HHS said:

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[48] Mosher & Jones, *supra*, at 25.

[49] Mosher & Jones, *supra*, at 6, 14 (cited by IOM Report at 103).

[50] Rachel K. Jones et al., *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 Persp. on Sexual & Reprod. Health 294, 297-98 (2002).

[51] Dep't of Health and Human Services, National Institutes of Health, *Female Contraceptive Development Program* (U01) (Nov. 5, 2013) (open for submissions until Feb. 28, 2014), http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html.

> [H]ormonal contraceptives have the disadvantage of having many undesirable side effects. In addition, hormonal contraceptives are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous thrombosis.... The oral contraceptive pill's failure rate among American women ranges from 9-30%. ... Furthermore, a recent report found that 40% of women were not satisfied with their current contraceptive method. ... Long-acting reversible contraception, which does not require daily compliance, has a much lower typical use failure rate. ... However, most of these methods are either devices, such as the IUD, or contain hormones. Use of intrauterine devices has only slowly gained acceptance in the US (from 0.8% in 1995 to 5.6% in 2006-2010), and IUDs are unlikely to be used by the majority of women desiring contraception.

A recent federal government report also acknowledged women's high rates of dissatisfaction and discontinuation (30 to 50%), especially of both longer acting and hormonal forms of contraception.[52] This is confirmed in another recent report by a leading contraception interest group, which estimated that nearly 40% of women who have used a "modern method" of contraception discontinue use

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[52] Daniels, Mosher & Jones, *supra*, at 8.

usually within one year or two, and most often hormonal forms.[53]

In support of its claim about the nexus between free contraception and increased usage, the IOM Report upon which the government relies[54] in turn relies upon inapposite studies. These studies examine cost as a factor affecting *both* men and women,[55] or the cost of preventive health care *generally*, not of contraception or ECs.[56] And the cited Hudman and O'Malley article[57] does not even consider contraception, and acknowledges that the

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[53] Sarah Castle & Ian Askew (Population Council), *Contraceptive Discontinuation: Reasons, Challenges and Solutions*, (Dec. 2015), http://ec2-54-210-230-186.compute-1.amazonaws.com/wp-content/uploads/2015/12/FP2020_ContraceptiveDiscontinuation_SinglePageRevise_12.16.15.pdf.

[54] 78 Fed. Reg. 39873, n. 24, citing IOM Report, p. 19; and Br. in Opp. 21, citing IOM Report 102-09.

[55] Henry J. Kaiser Family Found., *Impact Of Health Reform On Women's Access To Coverage And Care* 3 (2010), http://www.kff.org/women-shealth/upload/7987.pdf.

[56] *See* IOM Report at 19 (citing Sheila D. Rustgi et al., *Women at risk: Why many women are forgoing needed health care* (The Commonwealth Fund (2009)); Geetesh Solanki et al., *The direct and indirect effects of cost sharing on the use of preventive services*, 34 Health Services Research 1331 (2000); Amal N. Trivedi et al., *Effect of cost sharing on screening mammography in Medicare health plans*, 358 New Eng. J. of Med. 375 (2008) (considering, collectively, cancer screenings, dental exams, mammograms, and Pap smears).

[57] IOM Report at 109 (citing Julie Hudman & Molly O'Malley, Henry J. Kaiser Family Found., *Health Insurance Premiums and Cost-Sharing: Findings From the Research On Low-Income Populations*, 1 (2003), http://www.kff.org/medicaid/upload/Health-Insurance-Premiums-and-Cost-Sharing-Findings-from-the-Research-on-Low-Income-Populations-Policy-Brief.pdf.

studies it reviewed do not consistently find *any* link between cost-sharing and usage.

Both HHS' earlier submissions in Mandate litigation,[58] and the IOM Report,[59] suggest that one of the Mandate's goals is to increase usage of LARCs (which have higher upfront costs), "especially among poor and low-income women most at risk for unintended pregnancy."[60] The Mandate is not, however, directed to these groups of women; and the employed women to whom it is targeted already use LARCs more.[61]

Furthermore, regarding the claimed greater effectiveness of LARCs for reducing abortions and unintended pregnancies, the widely cited St. Louis experiment wherein LARCS were associated with these outcomes, occurred under circumstances not relevant to the Mandate's target audience. In this experiment, researchers persuaded a large number of mostly poor and post-abortive women to adopt LARCs (moving their adoption from 5% to 75%). and contacted each woman seven times to encourage continued usage.[62] But HHS has already publicly declared that the general population of women of child-bearing age have voted with their feet to avoid

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[58] *Hobby Lobby*, Def. Mem. at 7.

[59] IOM Report at 109.

[60] IOM Report at 109.

[61] Mosher & Jones, *supra*, at 35.

[62] Jeffrey F. Peipert et al., *Preventing unintended pregnancies by providing no-cost contraception*, 120 J. Obstet. Gyn. 1291 (2012), www.ncbi.nlm.nih.gov/pubmed/23168752.

both IUDs, and LARCs containing hormones. [63] In other words and as noted above,[64] when free to choose, women often discontinue even technically "more effective" contraception. These choices prevail despite LARCs' low price over time. According to Planned Parenthood, because LARCs such as the IUD are used for many years, despite their upfront costs they average from seven to seventeen dollars monthly, and are priced by some providers on a sliding income scale. [65]

LARCs, especially IUDs,[66] and Depo-Provera, are also troubling due to their association with various adverse health outcomes. The latter is linked to increased HIV transmission rates.[67] Also LARCs do not protect against sexually transmitted infections ("STIs").[68] In the above-noted St. Louis experiment [69] STIs spiked noticeably over the period

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[63] *See* Dep't of Health and Human Services, National Institutes of Health, *Female Contraceptive Development Program (U01), supra.*

[64] *See* nn. 51-53.

[65] Planned Parenthood, *The IUD* (2014), https://www.plannedparenthood.org/learn/birth-control/iud. *See also The Real Costs of Birth Control, supra.*

[66] Tessa Madden, *Risk of Bacterial Vaginosis in Users of the Intrauterine Device: A Longitudinal Study*, 39 Sex. Trans. Diseases 217 (2012).

[67] Renee Heffron et al., *Use of Hormonal Contraceptives and risk of HIV-1 Transmission: A Prospective Cohort Study*, 12 Lancet Infec. Dis. 19 (2012).

[68] Planned Parenthood, *Should you Choose Long-acting Reversible Contraception?* (2014), https://www.plannedparenthood.org/ppmh/long-acting-reversible-contraception-right-you-41717.htm.

[69] Jeffrey F. Peipert et al., *Preventing unintended pregnancies by providing no-cost contraception, supra.*

of the study. [70] Additionally, women using LARCs may be more likely to believe that all relevant health consequences of sex – emotional, psychological, and physical – are being managed, when they are not. These can have long-run negative impacts upon girls and women.

B. Even if the Mandate could increase usage of contraceptives and ECs, the government does not demonstrate that this will lead to lower rates of unintended pregnancy and abortion.

The government asserts that free contraception and ECs will lead to lower rates of unintended pregnancies and abortions,[71] but offers no reliable evidence for this claim.

First, the difficulty of measuring "unintended pregnancies," is well known,[72] as conceded by IOM itself in a 1995 report.[73] "Unintended" can mean unwanted or mistimed. Interpretation and memory can change over time. Partners can disagree. The one and only study relied upon by the IOM Report and HHS to claim a current 49% unintended

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[70] Ctrs. for Disease Control, Div. of STD Prevention, *Sexually Transmitted Disease Surveillance 2010*, 93-95, 113, 119-20, 127, 129 (2011), http://www.cdc/gov/std/stats10/surv2010.pdf.

[71] Br. in Opp. 21.

[72] Jessica D. Gipson, et al., *The effects of unintended pregnancy on infant, child, and parental health: a review of the literature*, 39 Studies in Family Planning 18 (2008).

[73] Inst. of Med., *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families* (1995), 21-25 [hereafter "IOM 1995 Report"].

pregnancy rate[74] suffers noticeably from such flaws. To reach the sum total of "unintended pregnancies," the authors added together "unwanted" and "mistimed" pregnancies, to pregnancies toward which the woman was "indifferent." To this figure they added their own abortion estimate.

Second, even if one accepts the government's figures for unintended pregnancies, the materials it relies upon, as well as pertinent materials it ignores, show rising rates of unintended pregnancies and abortions over some periods of time during which contraceptive usage was rising. This is not only due to contraceptive and EC failure rates, and the wide variety of factors affecting pregnancy and abortion rates, but possibly also the phenomenon of risk compensation, discussed below.

Third, concerning contraceptive failure, the CDC estimates that 12.4% of all women using contraception will become pregnant each year.[75] Thus, even if the Mandate could boost contraceptive usage, contraceptive failure will constrain reductions in pregnancy.

Also, about half of all unintended pregnancies occur among women who *are* using contraception[76], due to method failure, or incorrect use. This

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[74] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 Persps. on Sexual & Reprod. Health 90 (2006).

[75] Mosher & Jones, *supra*, at 4.

[76] Guttmacher Inst., *Facts on Unintended Pregnancy in the United States*, 4 (2012), www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html.

dramatically limits the potential for increased usage to reduce unintended pregnancies. This potential is further limited given that unintended pregnancies are highly concentrated among women the Mandate will *not* affect: the poor. Guttmacher reports that poor women have six times the rate of unintended pregnancy of women at 200% or more of the poverty line.[77]

Fourth and finally, a significant body of literature suggests that rendering contraception and ECs more accessible can drive rates of unintended pregnancy and abortion up, not down, due to "risk compensation" effects whereby individuals who believe they are insured against risk engage in more risky behavior. One widely cited study suggests that this phenomenon helps to explain how access to contraception decreases teen pregnancy in the short run, but increases it in the long run.[78] Programs promoting ECs (covered by the Mandate) to teens are in fact regularly associated with increases in teen pregnancy and abortion rates.[79] In a meta-analysis of 23 studies, Princeton's Dr. Trussel (upon whom the

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[77] Guttmacher Inst., *Unintended Pregnancy in the United States* (2013), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html.

[78] Peter Arcidiacono et al., *Habit Persistence And Teen Sex: Could Increased Access To Contraception Have Unintended Consequences For Teen Pregnancies?* (2005), http://public.econ.duke.edu/~psarcidi/addic ted13.pdf.

[79] Jose Luis Duenas et al., *Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997-2007*, 83 Contraception 82 (2011) (over ten years in Spain, a 63% increase in contraceptive use was accompanied by a 108% increase in abortion rate); *see also* David Paton, *The Economics of Family Planning and Underage Conceptions*, 21 J. Health Econ. 207 (2002).

IOM relies[80]) concluded that "*no* study has shown that increased access to [Plan B, an EC] reduces unintended pregnancy or abortion rates on a population level."[81] A study cited by the IOM Report concludes similarly.[82] Furthermore, it has been recently disclosed that well-known forms of ECs are less effective for women whose weight approximates the "average" American woman,[83] and "completely ineffective" for women weighing 11 pounds more than this. The National Institutes of Health ranks 36% of U.S. female adults as obese.[84]

Regarding adults, a growing body of scholarship[85] indicates that the persistence or worsening of high rates of unintended pregnancy, abortion, STIs, and nonmarital births are the

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[80] IOM Report at 108.

[81] Elizabeth G. Raymond, James Trussel & Chelsea B. Polis, *Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review*, 109 Obstetrics & Gynecology 181 (2007) (emphasis added).

[82] IOM Report at 108 (citing Debbie Postlethwaite, et al., *A comparison of contraceptive procurement pre-and post-benefit change*, 76 Contraception 360, 363 (2007)).

[83] Molly Redden, *New Warning: Morning-After Pill Doesn't Work for Women Over 176 Pounds*, Mother Jones (Nov. 25, 2013), http://www.motherjones.com/environment/2013/11/plan-b-morning-after-pill-weight-limit-pounds.

[84] Dept. of Health & Human Servs., Nat. Insts. of Diabetes and Digestive and Kidney Diseases, *Overweight and Obesity Statistics* (Oct. 2012), http://www.niddk.nih.gov/health-information/health-statistics/Pages/overweight-obesity-statistics.aspx.

[85] John Richens et al., *Condoms and Seat Belts: the Parallels and the Lessons*, 355 The Lancet 400 (2000); Michael M. Cassell et al., *Risk compensation: the Achilles' heel of innovations in HIV prevention?*, 332 Brit. Med. J. 605 (2006), www.bmj.com/cgi/pdf_extract/332/7541/605?ct.; Timothy Reichert, *Bitter Pill*, 203 First Things 25 (2010).

"logical" results of the new marketplace for sex and marriage made possible by increasingly available contraception and legal abortion. In perhaps the most well-known paper on this subject, *An Analysis of Out-of-Wedlock Childbearing in the United States*,[86] co-author and Federal Reserve Chair Janet Yellen describes women's immiseration via increased participation in nonmarital sexual relations without any expectation of marriage, as a result of the "technology shock" constituted by the increased availability of both contraception and abortion, which increased expectations that sex must constitute part of nonmarital romantic relationships. The government never considers or challenges this literature.

In fact, the government cites *no* sources in its brief for the claim that greater usage of contraception will reduce unintended pregnancies nationally; it simply assumes causation. In the IOM Report upon which the government usually relies, however, two studies are cited:[87] one by Santelli (an IOM Commission member) and Melnikas[88] and the other by Guttmacher.[89] Neither considers the entire U.S. population for all the years in which access to contraception has expanded, but only portions of the

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[86] Akerlof, Yellen & Katz, *An Analysis of Out-of-Wedlock Childbearing in the United States*, *supra*.

[87] IOM Report at 105.

[88] John S. Santelli & Andrea J. Melnikas, *Teen Fertility in Transition: Recent and Historic Trends in the United States*, 31 Ann. Rev. Pub. Health 371 (2010).

[89] Heather D. Boonstra et al. (Guttmacher Inst.), *Abortion In Women's Lives* (2006), http://www.guttmacher.org/pubs/2006/05/04/AiWL. pdf.

population over selected periods of time. [90] Neither claims to demonstrate a causal link between contraceptive usage and lowered rates of unintended pregnancy. Santelli and Melnikas claim only an "association," [91] and concede that they "do *not attempt to resolve this debate" about the "causes and consequences of teen pregnancy."* [92] They also acknowledge the phenomenon of risk compensation, [93] and the many factors that may influence teen pregnancy rates.[94] They estimate that abstinence, not contraception, contributed to at least 50% of the reported decline in teen pregnancy rates. [95] (Other scholars believe the figure is higher.[96])

The cited Guttmacher study also does not show that increased contraception usage helped reduce rates of unintended pregnancy. It states rather that "the decline in unintended pregnancy in the U.S. seems to have stalled," even with "nearly universal" use of contraceptives. [97] Two other Guttmacher studies show unintended pregnancy

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[90] Santelli & Melnikas (teens from 1990s to early 2000s); Boonstra (Guttmacher) (unmarried women, 1982 2002).

[91] *Ibid.*

[92] Santelli & Melnikas, *supra*, at 373, 377–78 (emphasis added).

[93] *Id.* at 375.

[94] *Id.* at 377-79 (mentioning the economy, population composition, family dynamics, social mores, the HIV/AIDS pandemic, and the media).

[95] *Id.* at 376.

[96] Joanna K. Mohn, Lynne R. Tingle & Reginald Finger, *An Analysis of the Causes of the Decline in Non-Marital Birth and Pregnancy Rates for Teens from 1991 to 1995*, 3 Adolesc. & Fam. Health 39 (2003) (67% of the decline attributed to abstinence and reduced sexual activity).

[97] Boonstra, *supra*, at 32.

rates rising from 44.7% during 1994[98] to 51% by 2001, and remaining flat or edging higher through 2006, [99] during the period when women's contraceptive usage *increased* from 80% to 86%.[100] A Guttmacher journal also reports that during the period from the 1970s to today — a period during which Guttmacher and the CDC agree that the percentage of women who had "ever used" contraception rose from about 90% to 99% — unintended pregnancy rates nationally rose from 35.4% to 49%.[101]

A CDC report tracking contraception usage from 1982 to 2008 concluded that "[c]hanges in contraceptive method choice and use have not decreased the *overall* proportion of pregnancies that are unintended between 1995 and 2008."[102] Another Guttmacher report on unintended pregnancy between 2001 and 2006, reached the same

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[98] Stanley K. Henshaw, *Unintended Pregnancy in the United States*, 30 Fam. Plan. Persp. 24 (1998).

[99] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 Persps. on Sexual & Reprod. Health 90 (2006); Mosher & Jones, *supra*, at 376-77.

[100] IOM Report at 105 (citing Boonstra et al., *supra*, at 18).

[101] Christopher Tietze, *Unintended Pregnancies in the United States, 1970-1972*, 11 Fam. Plan. Persp. 186, 186 n.* (1979) ("A recent report estimates that in 1972, 35.4% percent of all U.S. pregnancies were 'unwanted' or 'wanted later,' thus providing, from an independent source, an estimate very close to the one used here.").

[102] Jo Jones, William Mosher & Kimberly Daniels, *Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995*, *supra* at 1, 11.

conclusion, [103] despite CDC data showing that more women in the years between 2002 and 2008 were accessing "more effective" methods of contraception.[104]

It should also be remembered that the rise in unintended pregnancy rates from 44.7% to 51% between 1994 and 2001 — before they settled at about 49% from 2001 to 2006 — occurred during a time period when twenty-eight states passed contraceptive insurance mandates [105] covering private insurance.[106] A recent study of the empirical data from these states concludes that "there is certainly no evidence [that broad contraception mandates] reduce either the abortion rate or the unintended pregnancy rate." [107] It must also be remembered that there are a wide range of influences upon rates of unintended pregnancy (e.g. poverty, cohabitation, later marriage, and the destigmatizing of nonmarital sex and parenting[108]). The government never mentions these nor asks whether the studies cited by the IOM Report controlled for them.

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[103] Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities: 2006*, 84 Contraception 478 (2011).

[104] Mosher & Jones, *supra*, at 5.

[105] IOM Report at 108.

[106] These state laws are discussed in Nat'l Conf. of State Legislatures, *Insurance Coverage for Contraception Laws*, http://www.ncsl.org/issues-re- search/health/insurance-coverage-for-contraception-state-laws.aspx.

[107] Michael J. New, *supra* at 368.

[108] Guttmacher Inst., *Facts on Unintended Pregnancy in the United States* (2012), *supra*.

Other studies the government overlooks question or contradict its claims about the national effects of increased contraception usage. IOM's 1995 report on unintended pregnancy concludes, for example, that it is a "health condition of women for which little progress in prevention has been made despite the availability of safe and effective preventive methods."[109] A 2010 IOM Report states that: "there has been no major progress in prevention of unintended pregnancy...."[110]

The government also claims that free contraception and ECs will reduce abortions[111] without offering any sources. Again, this claim seems intuitively true on an individual scale, yet has not succeeded on a national scale. The IOM Report bases its claim upon one Guttmacher study[112] reporting that between 1982 and 2002 there was a 6% rise in the proportion of unmarried women using contraception, and a decline in abortion rates.[113] But this study considers only unmarried women, and only for a 20 year period. It variously claims that increased contraceptive usage "accompanied" or "contributed" to diminished abortion rates.[114] It makes no attempt to control for the myriad factors affecting abortion rates. This same study admits that early society-wide adoption of contraception often results in "an increase in both contraceptive use and abortion," but claims that over time abortion

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[109] IOM1995 Report at 104.
[110] Inst. Of Med., *Women's Health Research: Progress, Pitfalls, And Promise*, 143 (2010).
[111] Br. in Opp..21.
[112] Boonstra, *supra*, at 18.
[113] *Id.* at 18.
[114] *Ibid.*

rates fall.[115] The data does not bear this out. The study only considered data from 1983 to 2002.[116] The chart it references omits the years 1970 to 1982, during which time access to contraception was rapidly rising via the federal Title X program, while abortion rates were *climbing* not falling – from 14 per 1,000 women in 1973 to 24 per 1,000 in 1982. It was only after this simultaneous *rise* in rates of contraception usage and abortion rates for about 23 years post-Title X (a large federal contraception program), that abortion rates began to fall, although they remained fairly high, fell slowly, and never fell below their earliest 1970s rates.[117]

C. Even if free contraception and ECs could lead to fewer unintended pregnancies, the government has not linked unintended pregnancy with specific health outcomes for women.

While the government's brief does not specify how unintended pregnancy injures women's health,[118] its published regulations make specific claims about smoking, drinking, depression and violence.[119] Nowhere, however, does the government or the IOM Report it cites demonstrate this nexus. There is further the real scientific possibility. discussed above, that some contraceptives harm some women, via increased rates of STIs, nonmarital

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[115] *Id.* at 19.

[116] *Id.* at 17.

[117] Ctrs. for Disease Control, *Abortion Surveillance-U.S. 2000*, 52 Morbidity and Mortality Weekly Rep. No. SS-12, 17 (2003).

[118] Br. in Opp. 21.

[119] 78 Fed. Reg. 39872.

pregnancies and also abortion. Thus the unanswered question of whether the *net* health effects of the Mandate upon women's health are positive or negative.

Preliminarily, it should be noted that the IOM's own 1995 report on unintended pregnancy acknowledges that extant studies were *not* able to demonstrate the health effects the government here cites were "*caused by* or *merely associated with* unwanted pregnancy." [120] Similarly, the leading meta-analysis cited by the *current* IOM Report[121] concluded that "existing evidence on the impact of unintended pregnancy on ... health outcomes is mixed and is limited by an insufficient number of studies ... and by ... measurement and analytical concerns." [122] On the specific matter of a link between unintended pregnancy and domestic violence or depression, this cited meta-analysis concluded: "*causality is difficult if not impossible to show.*" [123] On the matter of any link between unintended pregnancy and women's smoking and drinking, an earlier IOM Report upon which the government relies concludes that even figures "associating" unintended pregnancy with these practices become insignificant where studies controlled for other causes.[124] Other studies indicate possibly reversed causation or a third factor –

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[120] IOM 1995 Report at 65 (emphasis added). Although the Report insists that it is not important to sort this out, this is irrational. Furthermore, RFRA's compelling interest standard requires a showing of causation. *See* Section I.

[121] *See* Jessica D. Gipson et al., *supra*.

[122] *Id.* at 20.

[123] *Ibid.* (emphasis added).

[124] IOM 1995 Report, 68-69, 75

women's pre-existing risk-taking preferences – accounting both for unintended pregnancy and smoking and drinking during pregnancy.[125] Finally, almost all mothers who smoke during pregnancy smoked before pregnancy.[126]

The IOM Report also proposes that domestic violence is a consequence of unintended pregnancy.[127] For this claim it cites a 1995 IOM report which *instead* concluded that studies could *not* establish causation.[128] Furthermore, the current IOM Report failed to divulge studies suggesting *reverse* causation.[129]

Further, on the matter of the link between contraceptive usage and women's health, the government fails to consider the ways in which contraception can directly harm women, though HHS has recently and publicly conceded the serious risks associated with hormonal contraceptives, which constitute a large fraction of FDA-recommended

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[125] Timothy S. Naimi et al., *Binge Drinking in the Preconception Period and the Risk of Unintended Pregnancy: Implications for Women and Their Children*, 111 Pediatrics 1136 (2003); Carolyn Westhoff et al., *Smoking and Oral Contraceptive Continuation*, 79 Contraception 375 (2009); Gregory J. Colman & Ted Joyce, *Trends in Smoking Before, During, and After Pregnancy in Ten States*, 24 Am. J. Preventive Med. 29 (2003).

[126] Colman & Joyce, *supra*, at 29-35.

[127] IOM Report at 103.

[128] IOM 1995 Report at 65.

[129] Jacquelyn C. Campbell et al., *The Influence of Abuse on Pregnancy Intention*, 5 Women's Health Issues 214 (1995); Patricia M. Dietz et al., *Unintended Pregnancy Among Adult Women Exposed To Abuse Or Household Dysfunction During Their Childhood*, 282 J. Am. Med. Ass'n 1359 (1999).

methods.[130] The IOM Report says only that "for women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated,"[131] and that there are "side effects" which are "generally considered minimal."[132] It adds an exception for "oral contraceptive users who smoke."[133] Especially when compared against HHS' recent admissions, this treatment is insufficient.

Rather, the government needs to engage evidence showing the association between easier access to LARCs[134] and ECs, and increased STI rates.[135] It needs to acknowledge that about 18% of American women smoke, which contraindicates for contraception usage.[136] The government should also acknowledge the irrationality of the argument that women with particular health conditions need free, expensive contraception to avoid pregnancy[137] while the medical associations devoted to these *very* conditions caution that these women likely face *greater* health risks from expensive hormonal

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[130] *See Female Contraceptive Development Program, supra.*

[131] IOM Report at 105.

[132] *Ibid.*

[133] *Ibid.*

[134] *See supra*, n. 70.

[135] Christine Piette Durrance. *The Effects of Increased Access to Emergency Contraception on Sexually Transmitted Disease and Abortion Rates*, Economic Inquiry (Dec. 5, 2012), http://onlinelibrary.wiley.com/doi/10.1111/j.1465-7295.2012.00498.x/ abstract.

[136] Am. Lung Ass'n, *Women and Tobacco Use*, http://www.lung.org/stop- smoking/about-smoking/facts-figures/women-and-tobacco-use.html.

[137] Br. in Opp. 21. In the course of the Hobby Lobby litigation, the government identified particular health conditions. *Hobby Lobby*, Pet. Brief at 47.

contraceptives, and thus should rather use the cheapest barrier or natural methods.[138]

Fourth, the government and the IOM Report fail to cite the significant and growing literature about direct harms caused by some contraceptives. Contemporary methods injure an unknown number of women every year. HHS bluntly conceded this in its recent solicitation to researchers to discover nonhormonal contraception, saying: "hormonal contraceptives have the disadvantage of having many undesirable side effects," and "are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous thrombosis."[139] NIH ranks 36% of U.S. female adults as obese.[140]

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[138] *See, e.g., Patient Information: Marfan Syndrome, Heart Disease & Pregnancy*, http://www.heartdiseaseandpregnancy.com/pat_mar_mom.htm; Amer. Congenital Heart Ass'n., *ACHA Q and A: Birth Control for Women with Congenital Heart Disease*, Heart Matters (2008), http://www.achaheart.org/Portals/0/pdf/Library%20Education/ACHA-Q-and-A-Birth-Control-for-Women-with-CHD.pdf (reporting that barrier methods are safe but risks are greater of hormonal methods, especially pills containing estrogen, and certain IUDS); Pulmonary Hypertension Ass'n, *Birth Control And Hormonal Therapy In Pah* (2002), http://www.phassociation.org/document.doc?id=1684 (reporting that barrier methods are "safest" and that "nearly half of ... specialists did not advocate using [pills] for their patients, and some actively discouraged patients from doing so ").

[139] *See Female Contraceptive Development Program*, *supra*.

[140] Dept. of Health & Human Servs., Nat. Insts. of Diabetes and Digestive and Kidney Diseases, *Overweight and Obesity Statistics* (Oct. 2012), *supra*.

The government also fails anywhere to mention that oral contraceptives, IUDs[141] and the Ring[142] continue to be the subject of myriad class action lawsuits which pharmaceutical corporations have paid hundreds of millions of dollars to settle. It overlooks recent expert literature showing a heightened risk of breast cancer for some pill users,[143] and important links between injectable LARCs and increased risk of HIV transmission.[144] It does not mention that leading cancer associations[145] and the World Health Organization ("WHO") refer to estrogen-progesterone oral contraceptives as "known

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[141] *See* Howard Ankin, *Bayer Healthcare Reaches Settlement in Yaz/Yasmin Lawsuits*, Ankin Law Office L.L.C. (May 7, 2012), http://www.ankinlaw.com/blog/bayer- healthcare-reaches-settlement-in-yazyasmin-lawsuits/; *Mirena IUD Lawsuit Update: Mirena IUD Adverse Event Reports to the FDA Exceed 45,000*, SFGATE (Nov. 26, 2012), http://www.sfgate.com/business/prweb/ article/Mirena-IUD-Lawsuit-Update-Mirena-IUD-Adverse-4067514.php#ixzz2GYR9cWxp.

[142] Marie Brenner, *Danger in the Ring*. Vanity Fair (Jan. 2014), http://www.vanityfair.com/politics/2014/01/nuvaring-lethal-contraceptive-trial.

[143] Ajeet Singh Bhadoria, et al., *Reproductive factors and breast cancer: A case-control study in tertiary care hospital of North India*, 50 Ind. J. of Cancer 316 (2013).

[144] Renee Heffron et al., *Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study*, *supra*.

[145] Am. Cancer Society, *Known and Probable Human Carcinogens Introduction*, http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens; Int'l Agency for Research on Cancer, *Monographs on the Evaluation of Carcinogenic Risks to Humans*, http://monographs.iarc.fr/ENG/Monographs/vol72/index.php.

carcinogens." [146] (The D.C. Court of Appeals relied upon the WHO's finding in rejecting HHS' claim that the Mandate will certainly improve women's health. [147])

In conclusion, the government has not shown that the Mandate will boost contraceptive usage, or that increased usage will reduce rates of unintended pregnancy or abortion. It offers no evidence showing that unintended pregnancy harms women's health in the ways it claims. Even if contraceptives have the indirect beneficial effects the government identifies, the government does not indicate the size of these benefits, or whether they outweigh the adverse health outcomes HHS concedes, or the immiseration of women in sex and marriage "marketplaces" shaped by contraception. In other words, the *net* effects of the Mandate upon the whole woman are unknown, and the government has offered no basis for concluding otherwise.

III. THE GOVERNMENT'S CLAIMS ABOUT THE MANDATE'S EFFECT ON WOMEN'S EQUAL ACCESS TO HEALTH SERVICES ARE UNPROVEN.

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[146] World Health Org., *Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment* (2005), http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf; Steven A. Narod et al., *Oral Contraceptives and the Risk of Breast Cancer in BRCA1 and BRCA2 Mutation Carriers*, 94 J. Nat'l Cancer Inst. 1773 (2002).

[147] *Gilardi v. U.S. Dep't of Health and Hum. Servs.*, 733 F.3d 1208, 1221 (2013) (referring to the contested evidence about contraceptives' health effects as a "tug-of-war...the government has neither acknowledged nor resolved....").

The government's latest claims about the relationship between the Mandate and women's health care costs are vague to the point of indecipherability. This alone disqualifies them from meeting the compelling interest standards of "particularity" or "specificity" Instead, the government is engaging in "speculation" and "prediction" (Section I.) The government states that the accommodation furthers its " 'compelling interest in providing women full and equal benefits of preventive health coverage' ", borrowing a phrase from the opinion of an appeals court judge below.[148] Quoting Justices Kennedy and Ginsburg from the *Hobby Lobby* decision, it further claims that the Mandate serves the government's " 'compelling interest in providing insurance coverage that is necessary to protect the health of female employees, coverage that is significantly more costly than for a male employee.' "[149]

But what do these vague phrases mean? Are they a restatement of the unproved (Section II.) assertion that contraception definitively advances women's health? Are they claims that contraception boosts the cost of women's healthcare over men's? If the latter, the government offers here no credible sources to support this claim, while *governmental* sources it fails to cite conclude differently.

The sources the government cites include the opinion of an appeals court judge, who herself offers

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[148] Br. in Opp. 20, quoting *Priests for Life v. U.S. Dept. of Health and Human Servs.*, 772 F.3d 229 (2014).

[149] *Id.* at 20, citing *Hobby Lobby*, 134 S. Ct. 2785-86 (Kennedy, J., concurring), and 134 S. Ct. 2799-2800 & n. 23 (Ginsburg, J. dissenting).

no sources for her conclusory statement that the Mandate "provides women full and equal benefits of preventive health coverage."[150] And those portions of the *Hobby Lobby* opinions on which the government relies, themselves rely on nonempirical sources.

To wit: they rather cite to HHS' *Hobby Lobby* brief,[151] which contains no data whatsoever about women's health care costs, or to Justice Ginsburg own interpretation of the government's compelling interest as a claim and a prediction that free IUDs will be widely taken up by women and thereby improve their health. In short, at the end of the government's long trail of citations for its claim that the Mandate provides women insurance coverage which is both "necessary" for their health and "significantly more costly" than men's, there is no data whatsoever.

Even the IOM Report's claims regarding women's higher health costs cite no sources addressing the costs of contraception,[152] or even the many components of women's health care costs.[153]

But the government does have data on the elements of men's and women's total health care costs that it fails to reference here. HHS's own Medicaid center attributes the higher cost of women's health care during child-bearing years, *not to contraception*, but to women's choosing to bear

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[150] *Priests for Life*, 772 F.3d at 264.

[151] Brief for HHS in No. 13-354, pp. 14-15.

[152] IOM Report at 19.

[153] Henry J. Kaiser Family Found., *Impact of Health Reform on Women's Access to Coverage and Care* (2010), *supra*.

children. [154] Further, HHS' own Centers for Disease Control links women's higher health care costs to women's far greater propensity to visit a variety of doctors and hospitals when they are younger. At older ages, men's costs then overtake women's. [155] In short, HHS provides no evidence whatsoever that forcing religious employers to attach free contraception to their insurance policies could advance equality between men's and women's health care costs.

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[154] *See* Ctrs. for Medicare & Medicaid Servs., *National Health Care Spending by Gender & Age, 2004 Highlights*, *supra*, at 1.

[155] Ctrs. for Disease Control, Nat. Cen. for Health Statistics, *Visits to physician offices, hospital outpatient departments, and hospital emergency departments by age, sex, and race: United States, selected years 1995-2011* (2012); Ctrs. for Disease Control, Nat. Cen. for Health Statistics, *Expenses for health care and prescribed medicine, by selected population characteristics: United States, selected years 1987-2010* (2012).

CONCLUSION

For the foregoing reasons, this Court should reverse the decisions of the courts below.

Respectfully submitted,

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